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| 10/756,802 | 01/13/2004 | Cynthia C. Bamdad | M1015.70070US01 | 1525 |
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Please find below and/or attached an Office communication concerning this application or proceeding.

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FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 29 January 2010 in which claims 115-125 were amended and new claims 135-143 were added. All of the amendments have been thoroughly reviewed and entered.

This action is further in response to an IDS submitted 26 February 2010. The foreign patent documents listed on the 1449 were not submitted and therefore have not been considered.

The previous rejection in the Office Action dated 25 January 2010 is withdrawn in view of the amendments. The previous indication of allowable subject matter is withdrawn in view of the prior art cited in the IDS of 26 February 2010.

New grounds for rejection, necessitated by the IDS, are discussed.

Claims 1, 119-122, 124-125, 127-129, 131-143 are under prosecution.

Claim Objections

2. Claim 135 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 120. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 119-120, 125, 135 are rejected under 35 U.S.C. 102(a) as being anticipated by Demers et al (Anal. Chem. 10/21/2000, 72 (22): 5535-5541).

Regarding Claim 1, Demers teaches immobilizing gold and alkanethiol-modified oligonucleotide tags on a common surface, allowing an interaction of the gold surface with mercaptoethanol and determining the interaction by identifying oligonucleotides separated from the surface (Scheme 1, page 5537).

Regarding Claim 119, Demers teaches the surface comprises gold (page 5536, right column).

Regarding Claims 120 and 135, Demers teaches the surface is a gold colloid particle (page 5536, right column).

Regarding Claim 125, Demers teaches identification of the tag via fluorescence (Abstract).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 119-122 and 124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Demers et al (Anal. Chem. 10/21/2000, 72 (22): 5535-5541) in view of Bamdad (WO 98/31839, published 23 July 1998).

Regarding Claims 121-122 and 124, Demers teaches the method wherein the surface is colloidal gold (page 5536, right column) but does not teach the particle has a self-assembled monolayer wherein the oligo and/or are immobilized vial a metal binding tag-metal-chelate linkage. However, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the method of Demers to any and all surfaces. The ordinary artisan would have been motivated to do so based on the known desire to determine surface coverage (Demers, page 5535, left column).

Furthermore, colloidal gold having the SAM layer and linkage was well known in the art at the time the claimed invention was made as taught by Bamdad.

Bamdad teaches a similar method comprising providing a target molecule and oligo tag, each immobilized on a common surface and allowing the target to participate in a reaction and determining participation by identifying the oligo tag on the surface (paragraph spanning pages 37-38) wherein the preferred supports are gold and have a self-assembled monolayer whereby the biological molecules are immobilized vial a

Art Unit: 1634

metal binding tag-metal-chelate linkage (pages 6-9). Bamdad teaches the supports provide for the detection of a conformation change in single molecules and is inexpensive, easily scalable and therefore useful for mass screenings (page 64, lines 9-28).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the self-assembled monolayer and metal binding tag-metal-chelate linkage taught by Bamdad to the gold particles of Demers. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success and for the benefit of an inexpensive means for mass detection of conformational changes at the single molecule level as taught by Bamdad (page 64, lines 9-28).

7. Claims 1, 119-122, 124-125, 128, 133, 135-137 are rejected under 35 U.S.C. 103(a) as being unpatentable over Demers et al (Anal. Chem. 10/21/2000, 72 (22): 5535-5541) in view of Dower et al (U.S. Patent No. 5,639,603, issued 17 June 1997).

Regarding Claims 1, 119-122, 124-125, 128, 133, 135-137, Demers teaches immobilizing gold and alkanethiol-modified oligonucleotide tags on a common surface, allowing an interaction of the gold surface with mercaptoethanol and determining the interaction by identifying oligonucleotides separated from the surface (Scheme 1, page 5537).

Dower teaches a similar method comprising providing a target molecule and oligo tag each immobilized on a common surface and allowing the target to participate

Art Unit: 1634

in a reaction and determining participation by identifying the oligo tag on the surface (Claims 1-8, Column 3, line 66-Column 4, line 18). Dower et al further teach the method wherein during the allowing step, the oligo identifier is immobilized (e.g. primer or distinct tag, Column 19, lines 60-63) and wherein determining includes separating the identifier (Column 18, line 54-Column 20, line 25).

Regarding Claims 119-120, Dower teaches the method wherein the surface comprises a gold colloid (Column 11, lines 35-38).

Regarding Claim 125, Dower teaches the method wherein the identifier is identified by fluorescent sequencing (Column 21, lines 37-50).

Regarding Claim 127, Dower teaches the method wherein the first surface is colloidal gold (Column 11, lines 35-38).

Regarding Claim 128, Dower teaches disclose the method wherein the oligo identifier is identified by a complementary oligo having a first portion complementary to the identifier i.e. regions of the oligo are complementary to primer-binding sites (Column 18, line 54-Column 19, line 35).

Regarding Claim 129, Dower teaches the method comprising allowing a first biological species, immobilized on a first surface to interact with a second biological species, immobilized on a second surface-and determining the interaction by identifying an interaction hybridization identifier that is complementary to a combination of a first oligonucleotide identifier immobilized on the first surface of the a second oligonucleotide identifier immobilized on the second surface (Claims 1-8, Column 3, line 66-Column 4, line 18 and Column 11, lines 35-38 and 57-60).

Regarding Claim 133, 135-137, Dower teaches the method wherein the oligo identifier is identified by PCR (Column 18, line 54-Column 20, line 25) and/or fluorescent sequencing (Column 21, lines 37-50) both of which require hybridization.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the techniques for identifying the oligos as taught by Dower to the methods of Demers. The artisan would have been motivated to do so with a reasonable expectation of success based on the well know and routinely practiced techniques taught by Dower.

8. Claims 1,125, 127, 132-134, 136, 137, 141-143 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burmer (WO 99/45149, published 10 September 1999, IDS of 2/10) in view of Still et al (U.S. Patent No. 5,565,324, issued 15 October 1996).

Regarding Claims 1, 125, 133, 136, 137, Burmer teaches immobilizing a biomolecule and oligo tag (i.e. encoding sequence) onto a bead (page 16, last paragraph), allowing the biomolecule to interact with it's target and detecting the interaction by detecting the tag (paragraph spanning pages 16-17). Burmer teaches the interaction is detected by amplifying the encoding sequence and/or tag (page 17, lines 6-8) using fluorescence, sequencing, hybridization and/or amplification (page 21, lines 16-17) but the reference does not teach separating the identifier prior to detecting.

Art Unit: 1634

However, Still teaches a similar method for detecting a target binding event by detecting a co-immobilized encoded tag (Abstract). Still further teaches that the tags are detachable thereby allowing the identification of reaction events at picomolar or lower concentration, wherein the detachable tags are amenable to rapid analysis by a variety of sampling systems (Column 5, line 57-Column 6, line 58). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the detachable tags of Still to the tag and/or encoding sequence of Burmer. One of ordinary skill in the art would have been motivated to do so for the expected benefit of rapid analysis of biomolecule binding events at very low concentrations as desired in the art (Still, (Column 5, line 57-Column 6, line 58).

Regarding Claim 127, 132, 134, 141-143, Burmer teaches immobilizing a biomolecule and oligo tag onto a bead (page 16, last paragraph), immobilizing a binding partner of the biomolecule onto a second bead and allowing the biomolecule to interact with it's target and detecting the interaction by detecting the tag (paragraph spanning pages 16-17). Burmer teaches the interaction is detected by amplifying the encoding sequence and/or tag (page 17, lines 6-8) wherein "well known" means are used to detect the resulting label (paragraph spanning pages 19-20) but the reference does not teach the release prior to amplifying or detecting.

Burmer teaches the interaction is detected by amplifying the encoding sequence and/or tag (page 17, lines 6-8) using fluorescence, sequencing, hybridization and/or amplification (page 21, lines 16-17) but the reference does not teach separating the identifier prior to detecting.

However, Still teaches a similar method for detecting a target binding event by detecting a co-immobilized encoded tag (Abstract). Still further teaches that the tags are detachable thereby allowing the identification of reaction events at picomolar or lower concentration, wherein the detachable tags are amenable to rapid analysis by a variety of sampling systems (Column 5, line 57-Column 6, line 58). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the detachable tags of Still to the tag and/or encoding sequence of Burmer. One of ordinary skill in the art would have been motivated to do so for the expected benefit of rapid analysis of biomolecule binding events at very low concentrations as desired in the art (Still, (Column 5, line 57-Column 6, line 58).

9. Claims 1, 119-122, 124-125, 127-129, 131-143 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burmer (WO 99/45149, published 10 September 1999, IDS of 2/10) in view of Still et al (U.S. Patent No. 5,565,324, issued 15 October 1996) as applied to Claims 1 and 132 above and further in view of Dower et al (U.S. Patent No. 5,639,603, issued 17 June 1997) and/or Bamdad (WO 98/31839, published 23 July 1998).

Claims 1 and 132 are discussed directly above.

Dower teaches a similar method comprising providing a target molecule and oligo tag each immobilized on a common surface and allowing the target to participate in a reaction and determining participation by identifying the oligo tag on the surface

Art Unit: 1634

(Claims 1-8, Column 3, line 66-Column 4, line 18). Dower et al further teach the method wherein during the allowing step, the oligo identifier is immobilized (e.g. primer or distinct tag, Column 19, lines 60-63) and wherein determining includes separating the identifier (Column 18, line 54-Column 20, line 25) wherein the surface comprises a gold colloid (Column 11, lines 35-38) wherein the identifier is identified by fluorescent sequencing (Column 21, lines 37-50) wherein the first surface is colloidal gold (Column 11, lines 35-38) wherein the oligo identifier is identified by a complementary oligo having a first portion complementary to the identifier i.e. regions of the oligo are complementary to primer-binding sites (Column 18, line 54-Column 19, line 35) wherein the oligo identifier is identified by PCR (Column 18, line 54-Column 20, line 25) and/or fluorescent sequencing (Column 21, lines 37-50) both of which require hybridization.

Dower teaches the method comprising allowing a first biological species, immobilized on a first surface to interact with a second biological species, immobilized on a second surface-and determining the interaction by identifying an interaction hybridization identifier that is complementary to a combination of a first oligonucleotide identifier immobilized on the first surface of the a second oligonucleotide identifier immobilized on the second surface (Claims 1-8, Column 3, line 66-Column 4, line 18 and Column 11, lines 35-38 and 57-60).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the techniques for beads of Dower to the methods of Burner. The artisan would have been motivated to do so with a reasonable

Art Unit: 1634

expectation of success based on the well know and routinely practiced techniques taught by Dower.

Regarding Claims 121-122 and 124, Burmer teaches the method wherein the surface comprises a bead (paragraph spanning pages 16-17), but the reference is silent regarding the bead or surface composition. However, the claimed beads and surface properties were well known in the art at the time the invention was made as taught by Bamdad.

Bamdad teaches a similar method comprising providing a target molecule and oligo tag, each immobilized on a common surface and allowing the target to participate in a reaction and determining participation by identifying the oligo tag on the surface (paragraph spanning pages 37-38) wherein the preferred supports are gold and have a self-assembled monolayer whereby the biological molecules are immobilized vial a metal binding tag-metal-chelate linkage (pages 6-9). Bamdad teaches the supports provide for the detection of a conformation change in single molecules and is inexpensive, easily scalable and therefore useful for mass screenings (page 64, lines 9-28).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the self-assembled monolayer and metal binding tag-metal-chelate linkage taught by Bamdad to the particles of Burmer and/or Demers. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success and for the benefit of an inexpensive means for mass detection

Art Unit: 1634

of conformational changes at the single molecule level as taught by Bamdad (page 64, lines 9-28).

Conclusion

10. No claim is allowed.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 26 February 2010 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

Art Unit: 1634

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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